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| 10/824,689 | 04/14/2004 | Arthur D. Ballard | 60305-USA | 8065 |

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| EXAMINER |
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HAIDER, SAIRA BANO

| ART UNIT | PAPER NUMBER |
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1711

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/824,689

Applicant(s)

BALLARD ET AL.

Examiner

Saira Haider

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-53 is/are pending in the application.
- 4a) Of the above claim(s) 20, 40, 43, 46 and 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-19, 21-39, 41, 42, 44-45, 47-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Claims 20, 40, 43, 46 and 53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/21/2006.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1-13, 15-16, 18-19, 21-36, 38-39, 41, 42, 44, 45, 47, 49, 51, and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Gennadios (US 6,214,376).
4. In reference to claims 1 and 3, Gennadios discloses a method for preparing thermoreversible gel films or capsules, the method comprising: heating, hydrating via the addition of an aqueous solution, stirring, and dissolving a film forming composition, wherein the process steps are completed in an apparatus. Once the composition is heated, it "thins out" and is converted from a viscous mass (dough-like) into a clear, free flowing liquid (i.e. molten), resulting in the formation of a molten composition. Gennadios does not expressly disclose that the molten composition is homogenous, however, it is inherent that since the composition is a free flowing liquid, it is molten and homogenous. This definition of homogenous molten composition is consistent with that provided by applicant in the remarks of 9/21/2006. Additionally, since the desired composition is formed, it is inherent that a sufficient amount of shear, temperature and residence time was provided. Solubilizing temperature, as per applicants' specification (see page 6, lines 11-14), is the temperature at which the composition becomes homogenous; therefore, since the desired homogenous molten composition is formed, it is inherent that the temperature utilized was at or

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above the solubilizing temperature of the composition. The composition is mixed in an apparatus, which is also referred to as a fluid mixing apparatus.

5. The homogenous molten composition is then transferred or introduced for processing into a conventional gelatin encapsulation machine, the composition is initially extruded in to a film. Wherein Gennadios would envisage utilization of an extruder capable of mixing the composition. It is noted that extrusion of the film at a temperature would inherently result in removing the volatile liquid, hence the extruder is recognized to function as a devolatilizer.

6. Subsequently, the extruded homogenous molten composition is gelled via cooling, resulting in the formation of gel films. Wherein it is inherent that in order for the composition to gel, the temperature must be at or below its gelling temperature.

7. Note, in reference to claim 47, it is held that the term comprising is inclusive and fails to exclude unrecited steps. *In re Horvitz*, 168 F 2d 522, 78 USPQ 79 (CCPA 1948).

8. In reference to claims 2, 15 and 16, the film forming composition comprises a hydrocolloid film former such as kappa-carrageenan, a plasticizer such as glycerin, a second film former such as malodextrin (a starch derivative), and a bulking agent such as malodextrin (a starch hydrolzylate). The pH control agent is optionally claimed, hence it is not a required component of the film forming composition.

9. Gennadios discloses a variety of components which may be included in the composition, such as colorants, flavorings, and the like (col. 5, lines 8-15). Hence meeting the limitations of claim 45.

10. In reference to claim 51-52, the film forming composition of Gennadios contains a hydrocolloid film former such as kappa-carrageenan and a plasticizer, such as solid corn syrup; however, solid corn syrup is multifunctional and can also be utilized as a bulking agent. Hence a

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composition comprising kappa-carrageenan and solid corn syrup is considered to contain a hydrocolloid film former and a bulking agent.

11. In reference to claims 9-13, since the patentees gel film is the same as the applicants, it is inherent that the patentees gel film has a break force strength of at least 6,000 grams. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, since the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

12. In reference to claims 21 and 23, Gennadios discloses a method for preparing thermoreversible gel films or capsules, the method comprising: heating, hydrating via the addition of an aqueous solution, stirring, and dissolving a film forming composition, wherein the process steps are completed in an apparatus. Once the composition is heated, it "thins out" and is converted from a viscous mass (dough-like) into a clear, free flowing liquid (i.e. molten), resulting in the formation of a molten composition. Gennadios does not expressly disclose that the molten composition is homogenous, however, it is inherent that since the composition is a free flowing liquid, it does not contain a solid state. Additionally, since the desired composition is formed, it is inherent that a sufficient amount of shear, temperature and residence time was provided. Solubilizing temperature, as per applicants' specification (see page 6, lines 11-14), is the temperature at which the composition becomes homogenous; therefore, since the desired homogenous molten composition is formed, it is inherent that the temperature utilized was at or above the solubilizing temperature of the composition. The composition is mixed in an apparatus, it is also referred to as a fluid mixing apparatus.

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13. The homogenous molten composition is then transferred or introduced for processing into a conventional gelatin encapsulation machine, wherein the composition is initially extruded in to a film. Wherein Gennadios would envisage utilization of an extruder capable of mixing the composition.

14. Subsequently, the extruded homogenous molten composition is gelled via cooling, resulting in the formation of gel films. Wherein it is inherent that in order for the composition to gel, the temperature must be at or below its gelling temperature.

15. The gel films are then fed through a series of rollers to counter-rotating dies which form, cut and fill soft capsules of various sizes.

16. Note, in reference to claim 49, it is held that the term comprising is inclusive and fails to exclude unrecited steps. *In re Horvitz*, 168 F 2d 522, 78 USPQ 79 (CCPA 1948).

17. In reference to claims 22, 35 and 36, the film forming composition comprises a hydrocolloid film former such as kappa-carrageenan, a plasticizer such as glycerin, a second film former such as malodextrin (a starch derivative), and a bulking agent such as malodextrin (a starch hydrolzylate). The pH control agent is optionally claimed, hence it is not a required component of the film forming composition.

18. In reference to claims 29-33, since the patentees gel film is the same as the applicants, it is inherent that the patentees gel film has a break force strength of at least 6,000 grams. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, since the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

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19. In reference to claims 22, 35 and 36, the film forming composition comprises a hydrocolloid film former such as kappa-carrageenan, a plasticizer such as glycerin, a second film former such as malodextrin (a starch derivative), and a bulking agent such as malodextrin (a starch hydrolzylate).

Claim Rejections - 35 USC § 103

20. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

21. Claims 17 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gennadios (US 6,214,376) as applied to claim 1 and 21, respectively, above.

22. From a Previous Office Action:

23. Gennadios discloses that the solubilizing temperature is above 130°F to below the boiling point of the working mixture (homogenous molten composition). However, Gennadios fails to disclose that the homogenous molten composition is heated, hydrated, mixed and solubilized at above atmospheric pressure. It would have been obvious to one of ordinary skill at the time of the invention to increase the pressure (to above atmospheric pressure) during the formation of the homogenous molten composition in order to decrease the time required to form the desired composition. Additionally, it would have been obvious, since the amount of pressure applied to the composition during the formation is manipulatable by an artesian, and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

24. Claims 48 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gennadios (US 6,214,376) as applied to claim 47 and 49, respectively, above, and further in view of Thanoo (US 5945126)

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25. From a Previous Office Action:

26. Gennadios discloses the claimed invention except for utilization of a Ross mixer as the apparatus. Hence attention is directed towards the reference. Thanoo teaches that non-static mixers, such as Ross mixers, are advantageous because one can control the mixing intensity independently of the flow rates of the feed streams into the device (12:13-40). Gennadios and Thanoo are analogous art because they are from the same field of endeavor, formation of pharmaceutical compositions.

27. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to utilize a Ross Mixer as the apparatus in process of Gennadios, as taught by Thanoo, in order to control the mixing intensity independently of the flow rates of the feed streams.

Response to Arguments

28. Applicant's arguments, filed 9/21/2006, with respect to the 112, second paragraph rejection (claims 4-8 and 24-28), and the claim objections (claims: 14, 18-20 and 38-46) have been fully considered and are persuasive, hence have been withdrawn.

29. Applicants have argued that Gennadios does not disclose the claimed step (ii), feeding the molten composition into at least one of a mixer, pump, or devolatilizer. Examiner has thoroughly considered applicants arguments and the references, and as mentioned in the rejection Gennadios envisages utilization of an extruder with a mixer, hence meeting the claimed limitation. The support for the envisagement of an extruder with a mixer is provided by the fact that Gennadios discloses that the composition is then transferred into a conventional gelatin encapsulation machine, wherein the films are formed by casting the solution on cooled rotating (e.g., metal such as steel) drums, and the films are fed through a series of rollers to counter-rotating dies which form, cut and fill capsules of various sizes (col. 6, lines 60-67). Hence clearly, Gennadios envisages utilization of a mixer.

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30. Applicants have argued that Gennadios does not disclose that the homogenous molten composition is highly viscous after heating. Examiner has thoroughly considered applicants arguments and the references, and although Gennadios discloses that the composition thins out after heating, Gennadios discloses that prior to that level of heating the composition is viscous mass (dough-like). It is noted that the level of heating is not claimed, by applicant, hence application of minor amounts of heat to the viscous mass (dough-like) composition of Gennadios would still result in formation of a highly viscous composition. Additionally, it is noted that the composition claimed by applicant is identical or similar to that of Gennadios, therefore the properties of the composition of Gennadios are considered to be identical or similar to that claimed by applicant.

31. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, since the prior art teaches the identical chemical structures, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The burden shifts to the applicant to show an unobvious difference. "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on 'prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

32. Since the prior art discloses the identical chemical structures, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The burden shifts to the applicant to show an unobvious difference. Note,

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that because the reference does not expressly teach or address the properties of the claimed invention, does not mean that the properties are not inherently disclosed. Disclosure of the same compound(s) inherently discloses the corresponding properties. The references cannot possibly teach or address all of the properties, but implicitly all of the properties are present.

33. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, examiner has provided rationale for one of ordinary skill in the art to vary the amount of pressure applied to the composition, wherein pressure is recognized as a general condition, and discovering the optimum or workable ranges involves only routine skill in the art. Applicant argues that there is no motivation to use a Ross Mixer. Examiner has provided motivation from the Thanoo reference for the advantages of using a Ross Mixer. Additionally, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Conclusion

34. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the

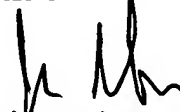
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mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Saira Haider whose telephone number is (571) 272-3553. The examiner can normally be reached on Monday-Friday from 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Saira Haider
Examiner
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James J. Seidleck
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